



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,575	11/14/2003	Stelios Tzannis	0180.00	1780

21968 7590 04/03/2006

NEKTAR THERAPEUTICS
150 INDUSTRIAL ROAD
SAN CARLOS, CA 94070

EXAMINER

KIM, YUNSOO

ART UNIT	PAPER NUMBER
----------	--------------

1644

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/714,575	Applicant(s) TZANNIS ET AL.	
	Examiner Yunsoo Kim	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-74 is/are pending in the application.
- 4a) Of the above claim(s) 1-30 and 60-74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/14/04, 6/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-74 are pending.

2. Applicants' election with traverse of Group II, drawn to claims 31-59, with the elected species of sucrose in the reply filed on 1/20/06 is acknowledged. Upon further consideration, species election has been withdrawn.

Applicants' traversal is based on search burden of Groups I/III/IV and II do not go beyond the search burden of Group II. As referred in the original restriction, these groups are distinct and have acquired a separate status in the art as shown by their different classification. They require non-co-extensive searches. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-30 and 60-74 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected invention.

Claims 31-59 are under consideration in the instant application.

3. Applicants' IDS filed on 4/14/04 and 6/11/04 are acknowledged.

4. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. It is noted that the written support for the particle mass median diameter of 7.5um-100um has not been provided from the provisional application 60/437,249.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 51 contains the trademark/trade name Tween-80. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982).

Art Unit: 1644

The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe polysorbate and, accordingly, the identification/description is indefinite.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 31-59 are rejected under 35 U.S.C. 102 (b) as being anticipated by U.S.Pat. No. 6,267,958 (IDS reference AK).

The '958 patent teaches a stable reconstituted formulation comprising an antibody of about 50mg/ml to about 400 mg/ml, diluent, buffer, sucrose as excipient (claims 1-8, 47 col. 17, lines 1-40).

The '958 patent further teaches the antibody being full length, fragments (Fab, F(ab)2), murine, chimeric, CDR grafted as well as humanized (col. 7-8, 10-12), IgE or IgG (e.g. anti-HER2, Examples 1-2), conjugated (e.g. heteroconjugates, col. 14, lines 18-27) and the excipient being buffer including phosphate, histidine (col. 14-15 overlapping paragraph), diluent being sterile water (col. 9, lines 39-45, col. 17, lines 1-40) and surfactants (e.g. polysorbate, col. 15, lines 35-60). In addition, the '958 patent further teaches packaging of the composition in vial and syringes (col. 18, lines 24-49).

Claim 59 is included in this rejection as the '958 patent teaches the referenced antibody formulation being 99+% intact (Tables 4-6). The claimed invention is drawn to a reconstituted antibody formulation comprising an antibody formed from a spray-dried powder and an excipient and the patentability of the product does not depend on its method of production. Thus, prior art teachings anticipate the claimed invention.

9. No claims are allowable.


Art Unit: 1644

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yunsoo Kim
Patent Examiner
Technology Center 1600
March 22, 2006


Patrick J. Nolan, Ph.D.
Primary Examiner
Technology Center 1600